(2) *Type of washing and chilling system used by the establishment.* Any post-evisceration washing or chilling processes that affect water retention levels in and microbial loads on raw products should be described. For poultry establishments, the main chiller types, identified by the mechanism used to transport the birds through the chiller or to agitate the water in the chiller, are the drag-through, the screw type, and the rocker-arm type.

(3) *Configuration and any modifications of the chiller system components.* A description of chiller-system configurations and modifications should be provided. The description should include the number and type of chillers in a series and arrangements of chilling system components, and the number of evisceration lines feeding into a chiller system. If there is a pre-chilling step in the process, its purpose and the type of equipment used should be accurately described. Any mechanical or design changes made to the chilling equipment should be described.

(4) *Special features in the chilling process.* Any special features in the chilling process, such as antimicrobial treatments, should be described. Also, the length and velocity of the dripping line should be described, as well as the total time allowed for dripping. Any special apparatus, such as a mechanism for squeezing excessive water from chilled birds, should be explained.

(5) *Description of variable factors in the chilling system.* The protocol should describe variable factors that affect water absorption and retention. In poultry processing, such factors are typically considered to be the time in chiller water, the water temperature, and agitation. The protocol should consider air agitation, where applicable. Additional factors that may affect water absorption and retention are scalding temperature and the pressure or amount of buffeting applied to birds by feather removal machinery, and the resultant loosening of the skin. Another factor that should be considered is the method used to open the bird for evisceration.

(6) *Standards to be met by the chilling system.* For example, the chilling system may be designed simply to achieve a reduction in temperature of ready-to-cook poultry to less than 40 °F within the time limit specified by the regulations, or in less time. As to the standard for pathogen minimization, the *Salmonella* pathogen reduction standards, as set forth in the PR/HACCP final rule, have been suggested. Although there is not yet an applicable *Salmonella* standard for turkeys, establishments are free to adopt practicable criteria for use in gathering data on turkeys under the protocols here suggested. Additional microbiological targets, such as *E. coli* or *Campylobacter* levels, or reductions in numbers of other microorganisms, may also be used.

(7) *Testing methods to be employed.* The protocol should detail the testing methods to be used both for measuring water absorption and retention and for sampling and testing product for pathogen reductions. The protocol should call for water retention and pathogen reduction tests at various chilling equipment settings and chilling time-and-temperature combinations. The method to be used in calculating water absorption and retention should be reproducible and statistically verifiable. With respect to the pathogen-reduction aspect of the testing, FSIS recommends the methods used for *E. coli* and *Salmonella* testing under the PR/HACCP regulations. The number of samples, the type of samples, the sampling time period, and the type of testing or measurement should be included in the protocol.

(8) *Reporting of data and evaluation of results.* The protocol should explain how data obtained are to be reported and summarized. The criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

(9) *Conclusions.* The protocol should provide for a statement of what the data obtained demonstrate and what conclusions were reached.

PART 500—RULES OF PRACTICE

Sec.

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

§ 500.1 Definitions.

(a) A ''regulatory control action'' is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A ''withholding action'' is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A ''suspension'' is an interruption in the assignment of program employees to all or part of an establishment.

§ 500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

(1) Insanitary conditions or practices;

(2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

(c) An establishment may appeal a regulatory control action, as provided in §§ 306.5 and 381.35 of this chapter.

§ 500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in § 417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§ 416.11–416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§ 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

(a) The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;

(b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in §§ 416.2–416.8 of this chapter due to multiple or recurring noncompliances;

(d) The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with § 310.25(a) or § 381.94(a) of this chapter;

(e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in § 310.25(b) or § 381.94(b) of this chapter.

§ 500.5 Notification, appeals, and actions held in abeyance.

(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

(1) State the effective date of the action(s),

(2) Describe the reasons for the action(s),

(3) Identify the products or processes affected by the action(s),

(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

(5) Advise the establishment that it may appeal the action as provided in §§ 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in § 500.4 of this part will:

(1) State the type of action that FSIS may take;

(2) Describe the reason for the proposed action;

(3) Identify the products or processes affected by the proposed action;

(4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and

(5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

(c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5 and 381.35 of this chapter.

(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§ 500.6 Withdrawal of inspection.

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H because:

(a) An establishment produced and shipped adulterated product;

(b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;

(c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;

(d) An establishment did not maintain sanitary conditions;

(e) An establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results as prescribed in § 310.25(a) or § 381.94(a) of this chapter;

(f) An establishment did not comply with the Salmonella performance standard requirements as prescribed in §§ 310.25(b) and 381.94(b) of this chapter;

(g) An establishment did not slaughter or handle livestock humanely;

(h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or

(i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

§ 500.7 Refusal to grant inspection.

(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:

(1) Does not have a HACCP plan as required by part 417 of this chapter;

(2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;

(3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;

(4) Has not demonstrated that livestock will be handled and slaughtered humanely; or

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.

(b) FSIS will provide written notification that:

(1) Explains the reason for rescinding or refusing the approval;

(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and

(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.

(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.